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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/766,350	12/13/1996	MALAYA CHATTERJEE	304142000321	7381

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1642	42

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/766,350	CHATTERJEE ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,23,26-30,32-65,67-76 and 78-104* is/are pending in the application.

4a) Of the above claim(s) *6-19,38,41,44-53,57 and 58* is/are withdrawn from consideration.

5)☒ Claim(s) *91, 95, and 98-103* is/are allowed.

6)☒ Claim(s) *1-5,20,23,26-30,32-37,39,40,42,43,54-56,59-65,67-76,78-90,92-94,96, and 97* is/are rejected.

7)☒ Claim(s) *104* is/are objected to.

8)☒ Claim(s) *1-20,23,26-30,32-65,67-76 and 78-104* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply.*

DETAILED ACTION

1. The amendment filed August 11, 2003 in Paper No. 39 is acknowledged and has been entered. Claims 21, 22, 24, 31, and 77 have been canceled. Claims 1, 20, 23, 39, 54, 56, 84, and 92 have been amended. Claims 98-104 have been added.

2. Claims 1-20, 23, 26-30, 32-65, 67-76, and 78-104 are pending in the application. Claims 6-19, 38, 41, 44-53, 57, and 58 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made with traverse in Paper No. 9.

3. Claims 1-5, 20, 23, 26-30, 32-37, 39, 40, 42, 43, 54-56, 59-65, 67-76, and 78-104 are currently under prosecution.

Election/Restrictions

4. Applicants' request for rejoinder of presently excluded method claims is acknowledged. In the Office action mailed October 3, 1997 (Paper No. 7), the examiner required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections Withdrawn

5. Unless specifically reiterated below, the grounds of objection and rejection set forth in the previous Office action mailed February 11, 2003 (Paper No. 37) have been withdrawn.

Lack of Compliance to 37 CFR §§ 1.821-1.825

6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR §§ 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Claim 79 presently recites an amino acid sequence, which is not properly identified by the sequence identification number corresponding to the same sequence

recited in the sequence listing. Amending claim 79 to recite this sequence identification number meet the requirements. If necessary to correct the deficiency, Applicant should submit substitute paper and computer-readable copies of the sequence listing, together with a statement that both copies are the same and include no new matter, as indicated on the attached Notice to Comply.

Applicant is given the same period of time within which to reply to this Office action to comply with the sequence rules set forth under 37 CFR §§ 1.821-1.825. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Specification

7. The specification is objected to because the use of numerous improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

An example of the improperly demarcated trademark appears in the specification at page 14, namely American Type Culture Collection™.

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

Claim Objections

8. Claim 104 is objected to because a polypeptide of claim 98 cannot comprise the light chain variable region containing the three complementarity determining regions (CDRs) of the monoclonal antibody 11D10 **and** the heavy chain variable region

containing the three CDRs of the monoclonal antibody 11D10, as required by claim 107, because claim 98 requires the polypeptide to comprise one or the other, *not both*.

Applicant has traversed this ground of objection at page 18 of the amendment filed August 11, 2003 (Paper No. 39), arguing that the term "or" does not exclude other sequences from the claim. Applicant has stated: "The three CDRs of the light chain *or* the heavy chain must be comprised (i.e included) within the claimed polypeptide [of claim 98], but other sequences may be included as well, in view of the term 'comprises'."

Applicant's argument has been carefully considered but not found persuasive. Claim 98 recites the polypeptide comprises element (a), i.e., "an immunoglobulin variable region containing three light chain complementarity determining regions (CDRs) of antibody 11D10", or element (b), i.e., "an immunoglobulin variable region containing three heavy chain CDRs of antibody 11D10". The claim does not recite, the polypeptide can comprise both element (a) and element (b); rather the claim recites that it must comprise one or the other. While "comprising" is open language, because the claim recites the polypeptide comprises element (a) **or** element (b), it would not be understood that the polypeptide could comprise both element (a) *and* element (b). It would only be understood that the polypeptide could comprise element (a) or element (b), and then some other undisclosed component(s).

Applicant can obviate this ground of objection by amending claim 98 to recite, for example, "or both" before "wherein" in line 3; but is duly noted that claim 98, insofar as the claim is drawn to a polypeptide comprising the light chain variable region containing the three complementarity determining regions (CDRs) of the monoclonal antibody 11D10 **or** the heavy chain variable region containing the three CDRs of the monoclonal antibody 11D10, would still be rejected under 35 USC § 112, first paragraph, for the reasons set forth below.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-5, 20, 23, 26-30, 33-37, 39, 40, 42, 43, 54-56, 59-65, 67-76, and 80-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making and using the mouse monoclonal antibody 11D10 and the hybridoma that produces mouse monoclonal antibody 11D10, does not reasonably provide enablement for making and/or using a monoclonal antibody produced by the progeny of the hybridoma that produces monoclonal antibody 11D10, or making and/or using said progeny. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1, 3, 20, 35, 39, and 73, and the claims that depend from these claims, are drawn to an antibody or a polypeptide comprising a portion of the antibody, wherein the antibody is produced by the hybridoma deposited under ATCC Accession No. HB-12020 *or progeny thereof*. The specification defines the term "progeny" of a hybridoma as "descendents of a hybridoma, which may or may not be completely identical to the original (parent) cell due to mutation or other adaptation, but that produce a monoclonal antibody that maintains the ability to escape immune tolerance, i.e., to cause an immune response against HMFG" (page 20, lines 8-11). However, the specification only describes the monoclonal antibody 11D10, which is produced by the hybridoma deposited under ATCC Accession No. HB-12020 without providing an amount of guidance, direction, and exemplification, which would be sufficient to enable the skilled artisan to make the claimed progeny. Furthermore, unless the progeny happens to produce an antibody that can be used in the same manner in which monoclonal antibody 11D10 can be used, the skilled artisan could not use the claimed progeny, or the antibody produced thereby, without the need to perform an undue amount of experimentation.

Applicant has traversed this ground of rejection in Paper No. 39, arguing that methods for culturing and obtaining progeny are well known in the art.

Applicant's arguments have been carefully considered but not found persuasive. For the reasons set forth in the previous Office action mailed February 11, 2003 (Paper No. 37), the amount of guidance, direction, and exemplification, which is disclosed in the specification, is not sufficient to enable the skilled artisan to have a reasonable expectation of successfully making and using the claimed invention without need to first perform an undue amount of experimentation. The factors, which have been considered in determining whether undue experimentation would be required to make and use the claimed invention, are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). These factors include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

11. Claims 1-5, 20, 23, 26-30, 33-37, 39, 40, 42, 43, 54-56, 59-65, 67-76, and 80-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3, 20, 35, 39, and 73, and the claims that depend from these claims, are drawn to an antibody or a polypeptide comprising a portion of the antibody, wherein the antibody is produced by the hybridoma deposited under ATCC Accession No. HB-12020 *or progeny thereof*. The specification defines the term "progeny" of a hybridoma as "descendents of a hybridoma, which may or may not be completely identical to the original (parent) cell due to mutation or other adaptation, but that produce a monoclonal antibody that maintains the ability to escape immune tolerance, i.e., to cause an immune response against HMFG" (page 20, lines 8-11). However, the specification only describes the monoclonal antibody 11D10, which is produced by the hybridoma

deposited under ATCC Accession No. HB-12020. The specification does not adequately describe a representative number of, or at least a substantial number of members of the claimed genus of polypeptides comprising an immunoglobulin variable region of the antibodies produced by the progeny of the hybridoma deposited under ATCC Accession No. HB-12020, which according to the specification may differ from the antibody produced by the parental cell, namely 11D10. Although the claim requires the polypeptide to be capable of stimulating a specific immune response against HMFG, this does not adequately describe the members of the claimed genus of polypeptides and antibodies, but merely states what the polypeptides must be capable of doing.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover,

because the claims encompass a genus of highly variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicants in the specification; nor have Applicants shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor have Applicants described distinguishing identifying characteristics sufficient to show that Applicants were in possession of the claimed invention at the time the application was filed.

Skolnick, et al (*Trends in Biotechnology* **18**: 34-39, 2000) disclose that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (see, e.g., the abstract; and page 34, *Sequence-based approaches to function prediction*). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see, in particular, the abstract and Box 2). The unpredictable nature of the art is further underscored by the teachings of Rudikoff, et al, Panka, et al, and Amit, et al (cited *supra*). Thus, one skilled in the art would not accept the assertion that a polypeptide comprising the three light chain and/or the three heavy chain CDRs of monoclonal antibody 11D10 would be capable of stimulating a specific immune response against HMFG. Therefore, as evidenced by the teachings of Skolnick, et al, the art is unpredictable.

The *Guidelines* state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus.

Applicant has traversed this ground of rejection in Paper No. 39, arguing to the contrary that the written description of the claimed genus of hybridomas is sufficient to meet the requirement set forth under 35 USC § 112, first paragraph.

Applicant's arguments have been carefully considered but not found persuasive. Given Applicant's disclosure, the skilled artisan could not recognize at least a substantial number of the members of the claimed genus; nor could the skilled artisan distinguish at least a substantial number of the members of the claimed genus from other hybridomas.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 32, 78, 79, and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 78, and 79 presently depend from claim 31; and claim 31 has been canceled. Accordingly, the metes and bounds of the claimed subject matter cannot be ascertained.

Claim 96 presently depends from claim 77; and claim 77 has been canceled. Accordingly, the metes and bounds of the claimed subject matter cannot be ascertained.

Double Patenting

14. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time-wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

15. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-5, 20, 23, 37, 39, 40, 59, 60, 69, 70, 74, 75, 88-90, 92-94, and 97 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 52, 53, and 55 of copending Application No. 10/367,506.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 52, 53, and 55 of copending Application No. 10/367,506 are drawn to a composition comprising an antibody comprising the light and heavy chains of monoclonal antibody 11D10, which is produced by the hybridoma having ATCC Deposit No. 12020.

This is a provisional obviousness-type double patenting rejection.

Conclusion

17. Claims 91, 95, and 98-103 are allowed. Claims 1-5, 20, 23, 26-30, 32-37, 39, 40, 42, 43, 54-56, 59-65, 67-76, 78-90, 92-94, 96, and 97, and 104 are not allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
December 15, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No.	Applicant(s)	
	08/766,350	CHATTERJEE ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Claim 79 recites an amino acid sequence of sufficient length to fall under the requirements set forth as 37 CFR 1.821-1.825; amending claim 79 to recite the SEQ ID NO of the matching sequence in the sequence listing can satisfy the requirements. If necessary, Applicant is advised to submit the substitute listing and statement, as indicated below.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
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